

REMARKS

Claims 1-2, 4-8 and 15-34 are presently pending in the captioned application with no claims being amended.

The Examiner has allowed claims 6-8 and 15-20. That indication is acknowledged with appreciation. However, the Examiner maintained the rejection of claims 1-2, 4-5 and 21-34 over U.S. Patent No. 6,103,894 ("Degelmann et al. '894").

Applicants now submit a § 1.132 Declaration by Yojiro Furukawa, one of the named inventors of the captioned application, showing that the compositions taught by Degelmann et al. '894 are amorphous and glass-like in nature in contrast to the presently claimed crystalline compositions. In particular, Fig.'s 1 and 2 of the Furukawa declaration are photomicrographs of the surface state of the powder sample of Example 3 of Degelmann et al. '894 taken by a high vacuum type scanning electron microscope. The Fig.'s 1 and 2 show that the known compositions have a smooth glass like surface. Fig. 3 is an X-ray diffraction graph of the same powder sample showing a lack of clearly defined diffraction spectra, which is indicative of an absence of crystal in the sample.

Based on the evidence presented in the Declaration, Applicants respectfully submit that the claimed invention of unallowed claims 1-2, 4-5 and 21-34 are indeed unobvious over the cited art and request withdrawal of the rejection.



USSN 10/030,981
UENO et al.

1. Rejection of Claims 1-2, 4-5 and 21-34
under 35 U.S.C. § 103(a)

RECEIVED

JAN 5 2004

TC-1700

The Final Office Action rejects claims 1-2, 4-5 and 21-34 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No.

6,103,894 ("Degelmann et al. '894"). The Office Action states:

Degelmann et al. teach a process for the hydrogenation of sugars selected from the group consisting of isomaltulose, leucrose, trehalulose, maltulose, and lactulose to sugar alcohols (col.1, line 52 to col. 2, line 37). The hydrogenation of isomaltulose can result in a composition comprising 1,1-GPM and a mixture of 1,6-GPS and 1,1-GPS in percentage ranges comparable to that instantly claimed. See Examples 3 and 9, and Tables 5 and 13 of Degelmann et al.

RECEIVED

JAN 05 2004

TC 1700

Although the reference does not specifically disclose separate amounts of 1,6-GPS and 1,1-GPS in the mixture, one of ordinary skill in the art would expect that the amounts of these two components would read upon the instantly claimed percentage ranges, absent the showing of convincing evidence to the contrary. That is, 1,1-GPS is present in the mixture of 1,6-GPS and 1,1-GPS in an amount within the respectively claimed range, the remaining amount of the mixture comprises 1,6-GPS in an amount within the claimed range of 1 to 50 wt.% 1,6-GPS (e.g., claim 2).

Because Degelmann et al. is considered to read upon the claims in their present form, any attending properties of the claimed composition (e.g., specific surface area) are considered to be encompassed by the composition of Degelmann et al. It is well settled that when a claimed composition appears to be substantially the same as a composition disclosed in the prior art, the burden is properly upon the applicant to prove

by way of tangible evidence that the prior art composition does not necessarily possess characteristics attributed to the CLAIMED composition. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed.Cir. 1990); In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980); In re Swinehart, 439 F.2d 2109, 169 USPQ 226 (CCPA 1971).

Applicants respectfully traverse the rejection because all the claimed limitations have not been taught by the cited reference. In particular, Degelmann et al. '894 only teaches **liquid** compositions obtained by hydrogenating a mixture of isomaltulose and trehalulose. Furthermore, the liquid compositions of Degelmann et al. '894 all have α -D-glucopyranosyl-1,1-sorbitol (1,1-GPS) content in a range of 2% or more, which is outside the presently claimed range of 0.01 to 1.5 wt%. The unexpected advantages of the solid crystalline composition over the liquid form also impart patentability onto the presently pending claims.

Turning to the rule, the Federal Circuit held that a *prima facie* case of obviousness must establish: (1) some suggestion or motivation to modify the references; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

In the present application, the independent claims contain the limitation of a **crystalline** solid composition which comprises

α -D-glucopyranosyl-1,1-mannitol (**1,1-GPM**),

α -D-glucopyranosyl-1,6-sorbitol (**1,6-GPS**), and

0.01 to 1.5 wt% of α -D-glucopyranosyl-1,1-sorbitol (**1,1-GPS**).

Degelmann et al. '894, however, does not teach a solid crystalline solid composition but only a **liquid** form used to solve the technical problems of process flow, handling of catalysts and reducing process costs over known methods of hydrogenating a sugar to sugar alcohol. See Degelmann et al. at col. 1, lines 46-48.

Although it is alleged in the Final Office Action in the "Response to Arguments" section of page 4, that Applicants mistakenly argued the teachings of U.S. Patent 6,414,138 (also with first named inventor Degelmann) rather than the cited Degelmann et al. reference (U.S. Patent 6,103,894), Applicants note that the cited Degelmann et al. '894 does indeed teach at col. 1, lines 46-

48 that the patented invention desirably "improves the process flow, the handling of the catalysts and process of the conventional process". See Response of June 30, 2003, at page 14, lines 5-9. Therefore, Applicants respectfully traverse the assertion that the previous Response incorrectly argued U.S. Patent 6,103,894 rather than the cited Degelmann et al. '894 reference.

Returning to the cited reference, it is noted that Degelmann et al. '894 teaches a process for hydrogenating a sugar to an aqueous sugar alcohol by contacting sugar with hydrogen in an aqueous solution at elevated temperatures and then in the presence of a catalyst. Degelmann et al. '894 does not provide any disclosure related to a solid, crystalline product as is presently claimed by the captioned application. Moreover, the compositions of Degelmann et al. '894 all have a 1,1-GPS content of 2% or more. In contrast, the presently claimed limitation specifically recites a 1,1-GPS content in a range between 0.01 to 1.5 wt%.

The Furukawa Declaration enclosed herewith verifies that the compositions of Degelmann et al. have a 1,1-GPS content outside the claimed ranges and that no crystal is contained therein. For example, a powder sample was obtained in the same manner as described in Example 3 of Degelmann et al. '894. In particular, a reduced palatinose solution containing 1,1-GPS was obtained by hydrogenating a mixture of palatinose and trehalulose prepared by

isomerizing cane sugar used as a raw material. The raw material solution was then concentrated to a solid content of about 50% and then poured into a stainless steel tray, fully cooled and left at room temperature overnight to be solidified. The solidified product was then ground with a hammer to obtain a powder sample.

As shown by Fig.'s 1 and 2 of the Furukawa Declaration, the surface state of the powder sample shows that the surface of each particle was smooth and did not contain any monocrystal when observed through a scanning electron microscope at a magnification of 50 to 3,000. Furthermore, Fig. 3 of the Declaration shows that a definite diffraction peak did not appear when an X-ray diffraction of this sample was carried out with an X-ray diffraction device. In other words, the powder sample contained almost no crystal.

Turning to a detailed analysis of the compositions of Degelmann et al. '894, it is noted that they have a 1,1-GPS content of 2% or more despite the Final Office Action's allegations that Examples 3 and 9 of Degelmann et al. '894 have a range of 1,1-GPs in percentage ranges comparable to that of the claimed invention. However, as clearly shown by the Declaration both Examples 3 and 9 of Degelmann et al. '894 contain 2% or more of 1,1-GPS.

In order to calculate the amount of 1,1-GPS, Applicants first turn towards the teachings in Example 1 of Degelmann et al. '894

which teaches the conversion reaction used in Example 3. In particular, isomaltulose was hydrogenated by using nickel, nickel oxide and "Sudchemie T-4190 RS 3mm", tungsten oxide catalyst, as catalysts in Example 1. Table 1 shows that 39.92% of 1,6-GPS was obtained by reacting 98% of isomaltulose (containing 2% of other component) for 1,320 minutes. Therefore, the conversion rate of isomaltulose into 1,6-GPS by this reaction was 40.73%, i.e. $39.92/98 \times 100 = 40.73\%$.

Since the reaction in Example 3 was carried out with the same reactor under the same conditions as in Example 1, the conversion rate of isomaltulose into 1,6-GPS in Example 3 is also 40.73%. Accordingly, 34.22% of isomaltulose was converted into 1,6-GPS because 84.02% of isomaltulose was used as an educt in Example 3 as shown in Table 4, i.e. $0.4073 \times 84.02\% = 34.22\%$.

Table 5 shows that the total amount of 1,6-GPS and 1,1-GPS obtained by the reaction of the invention of Degelmann et al. was 38.29%. Since the amount of 1,6-GPS is 34.22% of that amount, the amount of 1,1-GPS is 4.07%, which exceeds the presently claimed range of 0.01 to 1.5 wt%, i.e. $38.29\% - 34.22\% = 4.07\%$.

Turning to Example 9 of Degelmann et al. '894, it is noted that hydrogenation was carried out with a different reactor under different conditions from those of Example 1. Example 9 was carried out according to the processes of Examples 7 and 8. Using

the same analysis as that of Example 1, it can then be calculated that the conversion rate of isomaltulose into 1,6-GPS by the reaction of Example 8 is 47.59%. In other words, 46.7% of 1,6-GPS (Table 11) was obtained from 98.21% of isomaltulose (Table 10) yielding a conversion rate of 47.59%.

Since the same reactor and the same conditions as in Example 8 were employed in Example 9, the conversion rate of isomaltulose into 1,6-GPS in Example 9 is also 47.59%. Therefore, 1.24% of isomaltulose is converted into 1,6-GPS because 2.61% of isomaltulose is used as an educt in Example 9 as shown in Table 12.

Table 13 shows that the total amount of 1,6-GPS and 1,1-GPS obtained by the reaction of the invention of Degelmann et al. is 32.17%. Since the amount of 1,6-GPS was 1.24% of that amount, the amount of 1,1-GPS is **30.93%**, which exceeds the presently claimed range of 0.01 to 1.5 wt%.

The above results are summarized in the table below.

	GPS-6 Conversion rate	1,1-GPM	1,6-GPM	1,1-GPS
Degelmann et al. '894 Example 3	40.73%	54.57%	34.22%	4.07%
Degelmann et al. '894 Example 9	47.59%	60.82%	1.24%	30.93%
Present invention Example 1	---	59.4%	39.1%	0.9%

Although Degelmann et al. '894 teaches broad ratios, the specifically claimed range of a 1,1-GPS content in a range between 0.01 to 1.5 wt% is unobvious because the claimed limitation is not a result-effective variable for producing a crystalline product having the unexpectedly superior properties of low adhesion, low hygroscopicity, heat resistance, acid resistance, alkali resistance, excellent processability such as tablettability and granulability as well as possessing outstanding physiological properties such as low calorie content, being non-carcinogenic and having non-irritating insulin properties. See In re Antoine, 195 UPSQ 6 (C.C.P.A. 1977). The understanding that a particular ratio of the claimed components gives rise to a crystallized solid having desirable properties was unobvious at the time the invention was made.

Applicants note that any possible admonition that it would have been "obvious to try" to crystallize the sugar alcohol of Degelmann et al. '894 is improper. This is because in some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous choices until one possibly arrived at a successful result. Since Degelmann et al. '894 fails to provide any indication that the claimed limitations result in improved properties for solid sweeteners, it would not have been obvious to try to make a crystallized solid composition

incorporating the claimed limitations. See In re O'Farrell, 853 F.2d 894, 903, U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988).

Finally, it is noted that in Examples 3 and 9, out of the educts of Table 4 and Table 12, only isomaltulose was converted into 1,6-GPS by hydrogenation. One of ordinary skill in the art would know that when the reaction is carried out using the same catalyst in the same reactor under the same conditions, the conversion rate of isomaltulose into 1,6-GPS is the same. Therefore, the above calculation results are correct.

When a mixture obtained by acting a transferase prepared from cane sugar is hydrogenated, it contains 2% or more of 1,1-GPS as disclosed by Degelmann et al. '894. In the present invention, the amount of 1,1-GPS is reduced to 0.01 to 1.5 wt% and 1,1-GPS is in a crystalline form. Therefore, the present invention is clearly different from the teachings of Degelmann et al. '894 in technical concept.

Therefore, a *prima facie* case of obviousness has not been established. Degelmann et al. '894 cannot be applied against the presently claimed invention and no suggestion in the prior art existed at the time of invention that the claimed limitations result in an improved sweetner.

Accordingly Applicants respectfully submit that the presently claimed invention is unobvious over the cited reference and

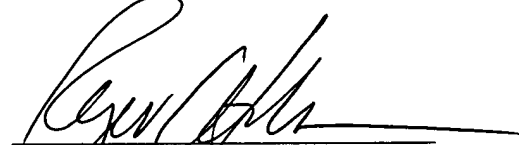
respectfully request reconsideration and withdrawal of the rejection under § 103.

CONCLUSION

In light of the foregoing, Applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of the pending claims and allow the pending claims. Favorable action with an early allowance of the claims pending is earnestly solicited.

Respectfully submitted,

SHERMAN AND SHALLOWAY


Attorney for Applicants
Roger C. Hahn
Reg. No. 46,376

SHERMAN AND SHALLOWAY
413 N. Washington Street
Alexandria, Virginia 22314
703-549-2282